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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,049	07/30/2004	Bernd Stahl	STAH3008/REF/LES	2144

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EXAMINER
KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
1623	

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02/14/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,049	STAHL ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32,36,37,41-43,50,51 and 53-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32, 36-37, 41-43, 50-51 and 53-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A Request for Continued Examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 11/26/2010 has been entered.

The Request for Continued Examination filed 11/26/2010 has been carefully considered. The following information has been made of record in the RCE filed for the instant application:

1. Claims 1-31, 33-35, 39-40, 44-49 and 52 have been canceled.

2. New Claims 54-61 have been added.

3. Claims 32, 36, 42 and 50 have been amended.

4. Remarks drawn to rejections under 35 USC 112, second paragraph, 102 and 103.

The following objections and rejections of record in the Final Action of 6/25/2010 have been overcome.

5. The rejection of Claims 32-53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been overcome in view of applicants' amendments to claim 32 and 50. The rejection of claim 33 for broad and narrow limitations has been rendered moot by cancellation of claim 33.

Claims 32, 36-37, 41-43, 50-51 and 53-61 are pending in the case.

Claim Objections

Claim 38 is missing and claims 39-40 are indicated as cancelled. Do applicants intend the status identifier of claims 38-40 as cancelled instead of claims 39-40? Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 37, 42 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Dosako et al (US 5,147,853).

Dosako teaches the administration of food containing GMP (glycomacropeptide) to a patient for treating infection by Epstein-Bar virus (Abstract; col. 2, lines 13-17; col. 1, lines 58-64; limitations of claims 32, 42-for glycomacropeptide and claim 50). The GMP is also administered for treating diarrhea col. 4, lines 29-59; limitation of claim 37; gastrointestinal tract infection).

Claim 50 is rejected under 35 U.S.C. 102(b) as being anticipated by Gilbert et al (WO 00/46379, of record).

Gilbert et al teach the synthesis of GD1a, GT1b and GT1c (page 38, lines 25-27; page 39, line 31 through page 40, line 8; active agents recited in claims 32 and 42) and pharmaceutical compositions of his compounds suitable for different modes of

administration (page 41, line 20 through page 42, line 3). Gilbert teaches a composition for oral administration comprising the gangliosides of his invention dissolved or suspended in water (page 42, lines 1-6). This constitutes a composition in the form of a beverage as in instant claim 50.

Claims 32, 37, 41, 42, 43, 50, 51, 53, 60 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Frankel et al (WO 00/45173, newly cited).

Frankel et al teach gangliosides GD1a and GT1b (page 5, lines 14-15; page 77, lines 13-18; limitations of claim 32) for the treatment of bacterial infections (page 6, lines 4-6; page 64, line 25 through page 65, line 2; limitation of claim 51). It is provided in the form of food product including supplement, additive and milk substitute (page 6, page 6, lines 19-23; page 7, lines 1-2; page 78, lines 4-13; limitations of claims 42, 50 and 60-61). It is suitable for administration to humans (page 6, lines 24-25; page 65, line 5; limitations of claim 53). The compositions can have flavors, gelatin (thickening agent) and liquid carriers (page 55, lines 1-5, lines 25-26; limitations of claim 43). Since the food composition comprising the active agents is also for oral consumption for treating bacterial infection this reads on the limitation of claims 37 and 41(gastrointestinal, blood and urogenital infections)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham **v.** John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 36-37, 41-43, 50 and 53-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel et al (WO 00/45173, newly cited) in view of Gilbert et al (WO 00/46379, of record), Prieto et al (US 6,045,854, newly cited) and Irie et al (US 4,557,931, newly cited).

The teachings of Frankel and Gilbert are as above. However, both do not teach compositions comprising disialyl-lacto-N-tetraose (DS-LNT) and disialyl-lacto-N-neo-

tetraose (DS-LNnT) as recited in instant claims 32 and 42 and the method of using the compositions for treating an infection.

Prieto et al teach compositions comprising Lacto-N-tetraose (LNT) and Lacto-N-neo-tetraose (LNnT; col. 3, lines 38 and 42). Even though these compounds do not have the disialyl group attached to them one of ordinary skill in the art will recognize that they have the same monosaccharide subunits that are present in the gangliosides (which have the sialyl groups) taught by Frankel and Gilbert et al. Therefore the sialyl groups can be attached to the Lacto-N-tetraose (LNT) and Lacto-N-neo-tetraose of Prieto et al to make food and dietetic compositions and the compositions can be used in a method of treatment of infections as taught by Frenkel and Gilbert.

Irie et al teach conjugating structurally close gangliosides with proteins as carriers for therapeutic purposes (col. 2, lines 32-55). From the teaching of Irie et al it is well known in the art to conjugate (or connect) gangliosides to polymers like proteins as carriers. One of ordinary skill in the art will recognize from the teaching of Irie that the Lacto-N-tetraose (LNT) and Lacto-N-neo-tetraose having the sialyl groups can also be connected to carriers like proteins and peptides and also glycolipids and gangliosides and used in the claimed methods of treatment.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ,82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

According to the rationale discussed in KSR above, the rationale in (A)-(C) above are seen to be applicable here since based on the prior art teachings, the claimed active agents are known to be useful for treating infections and gangliosides are known in the art to be conjugated to biopolymers like proteins for therapeutic purposes. Thus, it is obvious to combine prior art elements and make compositions comprising the instantly claimed active agents connected to carriers like proteins, peptides , etc.and use them in a method of treating infections. Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art. Product/method improvement is the motivation.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbert et al (WO 00/46379, of record) in view of Dosako et al (US 5,147,853, newly cited).

Gilbert et al teach the synthesis of GD1a, GT1b and GT1c (page 38, lines 25-27; page 39, line 31 through page 40, line 8; active agents recited in claims 32 and 42) and pharmaceutical compositions of his compounds suitable for different modes of administration (page 41, line 20 through page 42, line 3). The compositions include other agents/auxiliaries like water (water is seen as an auxiliary, a diluent, a moisturizing agent and a carrier). Gilbert teaches a composition for oral administration comprising the gangliosides of his invention dissolved or suspended in water (page 42, lines 1-6). The compositions comprising the oligosaccharides of Gilbert's invention can be administered as therapeutic generally in the range of about 0.5mg to 40g for a 70Kg patient (page 42 lines 21-31). This teaching of Gilbert can be used by one of ordinary skill in the art to adjust the dosage as in claim 36 since the amount that is effective will depend on the severity of the disease and the weight and general state of the patient. Single and multiple administrations can be carried out with dose levels being determined by the physician. Gilbert does not teach the dosage as recited in instant claim 36 and the administration of the active agents as a food/dietetic composition.

Dosoka et al's teaching is as above.

It can be recognized by one of ordinary skill in the art that the gangliosides taught by Gilbert and Dosaka can be added to food and/or dietetic compositions in the dosage range as recited in instant claim 36 in the claimed method of treatment since dosage can be adjusted. This is well known to the ordinarily skilled artisan and also well within the skill level of the artisan.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make food and/or dietetic compositions comprising the claimed active agent and use the said food/dietetic composition in the dosage as instantly recited and use it in a method of treatment of an infection since such compositions comprising the active agents and the general dosage range and the adjustment of the dosage is seen to be individually taught in the prior art as useful for the same purpose.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ,82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one

of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

According to the rationale discussed in KSR above, the rationale in (A) and (C) above are seen to be applicable here since based on the prior art teachings, the claimed active agents are known to be useful for treating infections. Thus, it is obvious to combine prior art elements and adjust the dosage of the active agents based on the teachings of the prior art to yield predictable results by making a food and/or dietetic composition of the same active agents and use them in a method of treating infections. Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art. Product/method improvement is the motivation.

Claims 53-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel et al (WO 00/45173, newly cited) in view of Irie et al (US 4,557,931, newly cited).

The teaching of Frankel et al is as above. However, Frankel do not teach or suggest connecting the sialyzed carbohydrates to carriers like polymers, carbohydrates, glycolipids, gangliosides, peptides and proteins as instantly claimed.

Irie et al teach conjugating structurally close gangliosides with proteins as carriers for therapeutic purposes (col. 2, lines 32-55). From the teaching of Irie et al it is well known in the art to conjugate (or connect) gangliosides to polymers like proteins as carriers. One of ordinary skill in the art will recognize from the teaching of Irie that the

gangliosides of Frankel et al can also be connected to carriers like proteins and peptides and also glycolipids and gangliosides and used in the claimed methods of treatment.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR, 550 U.S. at ,82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

According to the rationale discussed in KSR above, the rationale in (A)-(C) above are seen to be applicable here since based on the prior art teachings, the claimed active agents are known to be useful for treating infections and gangliosides are known in the art to be conjugated to biopolymers like proteins for therapeutic purposes. Thus, it is obvious to combine prior art elements and make compositions comprising the instantly claimed active agents connected to carriers like proteins, peptides, etc., and use them in a method of treating infections. Thus, the claimed invention as a whole is prima facie obvious over the combined teachings of the prior art. Product/method improvement is the motivation.

Response to Applicants' Arguments

In response to the amendments to the instant claims and applicants' arguments the rejections above are made of record.

Conclusion

Claims 32, 36-37, 41-43, 50-51 and 53-61

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1623

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